

K962816

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NOV 26 1996

Contact Individual:
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- 2) DEVICE NAME: Sperm Preparation Media

Proprietary Name: GenX Sperm Preparation Media

Common or Usual name: Culture Media

Classification Name: Sperm Preparation Media

According to the Classification Names for In Vitro Diagnostic Products (FDA 95-4246) we believe that this media belongs in one of the following classes:

CULTURE MEDIA, NON PROPAGATING TRANSPORT 83JSM
CULTURE MEDIA, GENERAL NUTRIENT BROTH 83JSC
CULTURE MEDIA, NON-SELECTIVE AND NON-DIFFERENTIAL 83JSG
CULTURE MEDIA, SUPPLEMENT 83JSK

- 3) ~~This product~~ *"Cervical Cap" old procedure prior to MQL procedure* is substantially equivalent to the Irvine Sperm Capacitation Media (product code HDR and K861188). This product has the same intended use, the same original formula, and the same basic ingredients.
- 4) Sperm Preparation Media is a culture media used to prepare sperm prior to Intrauterine Insemination (IUI) procedures. The preparation of sperm includes washing of the sperm and its separation from the semen.
The basic ingredients of this products as described in the Formulation section of the submission are sterile water, minerals, glucose, and penicillin. This product is provided in sterile bottles.
This products as indicated in the label is For In Vitro Use Only.

- 5) The intended use of this media is for *in vitro use* only, the same as the Irvine Sperm Capacitation Media (product code HDR and K861188).
- 6) Sperm Preparation Media has the same characteristics and the same chemical composition as the predicate device Irvine Sperm Capacitation Media (product code HDR and K861188).
Sperm Preparation Media is a mineral essential media with glucose and penicillin, which are the same basic ingredients as the Irvine Sperm Capacitation Media.